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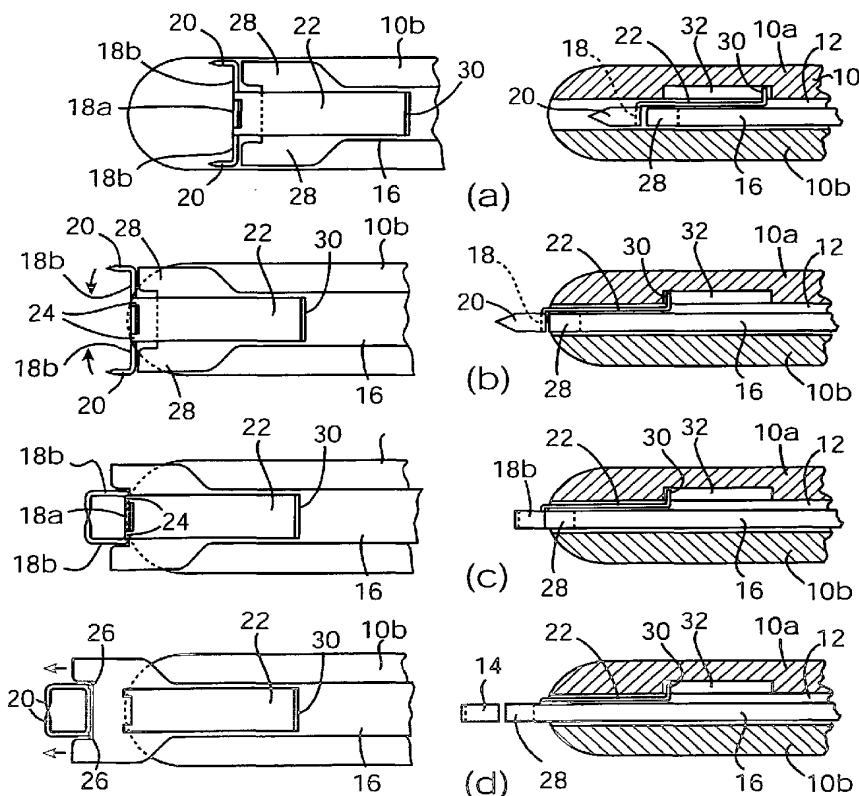
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[Continued on next page]

(54) Title: SURGICAL STAPLING DEVICE



(57) **Abstract:** A surgical stapler comprises an elongate housing 10 and a surgical staple 14 slidable longitudinally within the housing towards the free forward end thereof. The back 18 of the staple has a rearward extension 22. An actuator 16 is slidable forwardly within the housing for driving the staple towards the free end of the housing. An upstanding flange 30 on the extension 22 engages a stop 32 within the housing to restrain the back of the staple against forward movement of the actuator bends the staple to bring the free ends of the legs towards one another to close the staple. Further movement of the actuator then ruptures the join between the extension and the back of the staple to release the closed staple.



— *of inventorship (Rule 4.17(iv)) for US only*

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Surgical Stapling Device

This invention relates to a surgical stapling device.

5 Surgical stapling devices have been in existence for many years. They are routinely used in surgical procedures mainly for the purposes of effecting a wound closure. Some of the most popular applications include closing a skin incision end-to-end or end-to-
10 side anastomosis of internal (generally tubular) vessels such as the large bowel, etc. Current staplers are designed to deliver one or more staples in a serial fashion or a number of staples in one shot. Skin staplers, for example, deliver 30 or more staples in a
15 serial fashion. The staples are stacked within the device and during the firing operation one staple is advanced from the stack and delivered through the head of the device. During the following cycle another staple is advanced from the top of the stack and again
20 delivered through the head of the device and so on. In one shot devices such as a bowel anastomosis stapler the staples are prearranged in a linear or circular fashion and upon activation of the device all the staples are delivered through the head. Examples of
25 existing prior art as described above include US Patents 4,592,498, 5,289,963, 5,433,721 and 5,470,010.

The mechanism involved in forming a staple and releasing it from its forming mechanism is common to
30 the majority of surgical stapler devices. Generally the components include an anvil, a staple closing

actuator, and a staple release mechanism. The anvil is normally positioned in front of the staple and the actuator directly behind the staple. As the actuator advances the staple against the anvil the back section of the staple deforms around both ends of the anvil thereby transforming the staple from a generally U-shape to a generally rectangular shape. At this point the actuator generally retracts and the staple is released from the anvil either as a result of the anvil moving out of position and allowing the staple to move forward, or alternatively ejecting the staple over the anvil thereby releasing it from the device.

There are a number of problems associated with the mechanism as described above. Firstly, as the anvil is normally positioned in front of the staple it naturally becomes trapped between the back of the staple and the tissue into which it is being delivered causing the staple back to be spaced away from the tissue as opposed to lying tightly on its surface. This is a particular problem in the field of vascular puncture closure when it is desirable to keep the legs of the staple as short as possible so as to avoid having the legs of the staple within the vessel lumen.

Secondly, the method of releasing the staple from the anvil can be both complicated and unreliable. Metal springs are normally used which eject the staple over the anvil thereby affecting its release. However, should the spring fail to operate or is prohibited from

operating properly by virtue of some tissue blockage etc, the device will become trapped in-situ.

Alternative release mechanisms include mechanical means
5 of moving the anvil so that it is no longer in the path
of the staple as it releases from the device. Again
this generally involves very small metal components
with relatively small movements which can fail to
operate thereby leaving the staple trapped within the
10 device and attached to the tissue into which it has
been delivered.

Therefore there is a need for an improved surgical
stapling device which will facilitate closer
15 approximation of the staple back onto the surface of
the vessel into which the staple is being delivered and
a method of deforming the staple which does not include
the use of an anvil component and therefore will not
require the use of other components or mechanisms to
20 facilitate the release of the staple from the anvil.

According to the present invention there is provided a
surgical stapling device comprising an elongate
housing, a surgical staple slidable longitudinally
25 within the housing towards a free forward end thereof,
the staple having a back and two forwardly pointing
legs, an actuator slidable forwardly within the housing
for driving the staple towards the free end of the
housing, means for restraining the back of the staple
30 against forward movement beyond a predetermined point
such that further forward movement of the actuator

bends the staple to bring the free ends of the legs towards one another to close the staple, and means for releasing the closed staple, wherein the back of the staple has a rearward extension and the restraining
5 means comprises means for restraining the extension.

In a preferred embodiment the rearward extension is rupturably joined to the back of the staple, the staple being released by forward movement of the actuator
10 beyond the point at which the staple is closed while the extension is restrained, thereby to rupture the join.

In another preferred embodiment a rearward extension is created which is integral to the staple back. This
15 rearward extension creates a slot into which one end of an extension component is connected. Once the former has formed the staple around the anvil the extension is released from the staple during rearward movement of
20 the former.

The benefits of the invention over conventional stapling devices is that, firstly, as no anvil is required the staple can be advanced forward to a
25 position where the staple back is in direct contact with the tissue being stapled. This is of particular advantage when the staple legs must remain short but the level of penetration into the tissue must be assured. Secondly, because there is no anvil component
30 involved in the delivery mechanism, there is no requirement to add additional components so as to

facilitate ejection of the staple over or around the anvil component or alternatively to move the anvil component to a position which allows the staple to advance forward and free up the device.

5

Embodiments of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:

10 Fig. 1 is a perspective view of a staple with a restraining plate for use in an embodiment of the invention;

Figs. 2(a) to 2(d) are plan views (left hand column)
15 and equivalent sectional views (right hand column) of a stapling device according to the embodiment in successive stages of operation;

Fig. 3 is a perspective view of the staple and
20 actuator assembly of Fig. 2;

Fig. 4 is a perspective view of the forward tip of the actuator of Fig. 2; and

Figs. 5 to 12 are perspective view of further
25 embodiments of staple for use with a device according to the invention.

In the drawings the same reference numerals have been used for the same or equivalent parts.

30

Referring to Figs. 1 to 4, a surgical stapling device comprises an elongated housing or shaft 10 having upper and lower halves 10a and 10b defining between them a longitudinal channel 12 for slidably accommodating a staple 14 and a staple closing actuator 16 (in the plan views in the left hand column of Fig. 2 only the lower housing half 10b is shown). Only the free forward end of the housing 10 is shown in the drawings, since that is where the invention lies in the present embodiment.

10 The rear end of the housing 10 is preferably formed with a pistol grip and the movement of the various components to be described may be effected by a trigger acting through a cam system. Such an arrangement is described in Irish Patent Application S2000/0722 which

15 may be readily adapted to operate the device of the present embodiment.

The staple 14 is generally U-shaped, having a back 18 and two forwardly pointing legs 20. The free ends of the staple legs 20 are sharpened for ease of tissue penetration. Integral with the staple back 18 there is a rearwardly extending plate 22 which is attached to the upper edge of the centre section 18a of the staple back by a pair of narrow, relatively weak tabs 24. The

20 tabs are effectively thin metal bridges which connect the staple back to the plate 22. At the rear end of the plate 22 there is an upstanding flange 30 perpendicular to the plane of the plate 22. In this embodiment the staple 14 including the plate 22 and

25 flange 30 is made as an integral structure from stamped and bent sheet metal stock, for example, a malleable

30

metal or metal alloy such as stainless steel or titanium.

Adjacent to the tabs 24, at the junctions 26 between
5 the centre section 18a and the outer sections 18b of
the staple back on either side, and where in use the
staple back is designed to bend through an angle of 90°
as will be described, local deformation of the material
of the staple is provided so as to ensure that bending
10 takes place preferentially at those points.

The actuator 16 is an elongated rod having a forward
end which is forked to provide two arms 28 separated by
a recess 34. The lateral separation of the arms 28 is
15 slightly greater than the distance between the
junctions 26 on the back 18 of the staple.

The device is assembled (Fig. 2) with the actuator 16
extending longitudinally in the channel 12 with its
20 forked end facing towards the free forward end of the
housing 10. The staple 14 is positioned freely in
front of the actuator 16 with its back 18 transverse to
the axis of the housing 10 with the plate 22 extending
rearwardly across the top surface of the actuator. The
25 flange 30 extends up into a recess 32 in the top
housing half 10a. The actuator arms 28 are behind and
in alignment with the outer sections 18b of the staple
back.

30 In use, both the staple 14 and the actuator 16 are
initially retracted, Fig. 2(a), so that the flange 30

is adjacent the rear end of the recess 32 and the entire staple 14 is contained wholly within the housing 10. Upon operation of the trigger previously mentioned, or other operating mechanism, the actuator 5 16 is driven forwardly towards the free forward end of the housing 10. This drives the staple 14 before it by engagement of the actuator arms 28 with the outer sections 18b of the staple back.

10 At a predetermined point, Fig. 2(b), where the back of the staple is substantially level with the forward end of the housing 10, the flange 30 comes up against the front end of the recess 32. The flange 30 and front end of the recess 32 act as cooperating stop means 15 which, via the plate 22, restrain the centre section 18a of the staple back against further forward movement. Thus, as the actuator 16 continues to advance, the actuator arms 28 bend the outer sections 18b of the back of the staple forwardly through 90° to 20 bring the free ends of the staple legs 20 towards one another and deform the staple into a generally rectangular closed shape, Fig. 2(c).

At this point the base 36 of the recess 34 in the front 25 of the actuator 16 is abutting against the centre section 18a of the staple base. Now, since the plate 22 remains restrained by engagement of the stop means 30/32 further forward movement of the actuator 16 will rupture the tabs 24 thus freeing the staple from the 30 plate 22. At this point the cycle is complete.

Fig. 5 shows an alternative embodiment for the staple. It comprises a standard round wire staple 40 having a rearwardly extending restraining plate 22 with upstanding flange 30 attached to the centre section of the staple back by rupturable tabs 24. The tabs may be attached to the staple back by soldering, braising, laser welding, adhesive bonding, etc. The preferred process will ensure a consistent break-off force between the tabs and the staple back.

10

Referring now to Fig. 6, another embodiment of the staple is shown which includes two staples 14 disposed spaced apart one above and each having a respective rearwardly-extending restraining plate 22 joined thereto by rupturable tabs as previously described. In this case the rear ends of the parallel plates are joined by a common flange 30. In such a case the stapling device would be modified such that stop means on the housing 10 projected into the space between the upper and lower plates 22 and engaged the flange 30 between them to restrain the back of the staple. The double staple could be driven by two actuators 16, one disposed above the upper plate 22 and the other below the lower plate 22, or a single actuator could be used having upper and lower branches which embrace the plates 22 between them.

Fig. 7 shows another staple usable in the invention in which the centre section 18a of the staple back is enlarged, for example by forming it as a disk 42, so that the centre section 18a has a much greater area in

a plane normal to the longitudinal axis of the housing 10 than either of the outer section 18b. This configuration has particular application in the field of vascular puncture closure. The process of closing puncture holes using conventional staples may be enhanced using this method as the disk 42 on the staple back provides greater surface coverage of the puncture hole area thereby effecting haemostasis in a shorter time.

10

Fig. 8 shows a configuration which is essentially the double staple as described in Fig. 6 but for use in combination with a stapling device having a locator tube 44. The locator tube 44, which passes between the plates 22 through a hole (not shown) in the flange 30, is slidable axially within the housing 10 between a forward position wherein it projects beyond the free forward end of the housing 10 to enter a puncture site in a liquid-carrying vessel in a human or animal, thereby to locate the free end of the housing at the puncture site, and a rearward position wherein the locator tube is retracted into the housing. In use a guidewire (not shown) extends within the locator tube and emerges from the forward end of the tube, the tube 44 being tracked along the guidewire to the puncture site and the guidewire and tube being retracted into the housing prior to closure of the staples. A locator tube is described in the aforementioned Irish Patent Application S2000/0722, and it will be clear to one skilled in the art how to modify the embodiment shown in Fig. 2 to incorporate such a tube. This

30

configuration has particular relevance in the area of vascular puncture closure.

The staple configurations shown in Figs. 6 to 8 are, like the staple shown in Fig. 1, designed so that they are easily manufactured as integral structures from sheet metal using a conventional metal stamping and bending processes.

The embodiment of staple shown in Fig. 9 comprises a staple essentially as described with reference to Fig. 7 but without the attached plate 22. Instead, a rearwardly extending filament 46 is attached to the rear surface of the disk 42. In use, the stapling device is adapted to trap or hold the rear end of the filament 46 so that it becomes taut at the point where the staple back is level with the front end of the housing 10 so that further advance of the actuator will bend the outer sections 18b of the staple back to close the staple as previously described. At this point the actuator may advance further forward thereby shearing or detaching the filament from the back surface of the disk 42. Alternatively, the actuator may retract while simultaneously the device releases the filament at its rear end and consequently releasing the staple from the device. Examples of the filament material are Dacron, PLA, PGA and PLGA.

In Fig. 10 a staple configuration is shown similar to that in Fig. 3 except that the rupture tabs 24 are replaced with a slotted tab 50 which engages with an

upstanding flange 52 integral to plate 22. As the former advances forward to form the staple the back is held in position by the plate 22. Once forming is complete the former component retracts while
5 simultaneously causing the plate 22 to move down disengaging the flange 52 from the staple slot 50 allowing it to separate from the stapler device.

Figs. 11 and 12 illustrate further embodiments of this
10 principle. In Fig. 11 the flange 52 engages a band 54 which is formed integrally with an lies parallel to the back 18 of the staple. In Fig. 12 a pair of L-shaped cylindrical arms engage a channel section 58 of the staple back 18 to restrain the staple during forming.
15 When forming is complete the former retracts while simultaneously causing the arms 56 to be pushed outwards, away from one another and out of engagement with the channel section 58.

20 The invention is not limited to the embodiments described herein and may be modified or varied without departing from the scope of the invention.

Claims

1. A surgical stapling device comprising an elongate housing, a surgical staple slidable longitudinally
5 within the housing towards a free forward end thereof, the staple having a back and two forwardly pointing legs, an actuator slidable forwardly within the housing for driving the staple towards the free end of the housing, means for restraining the back of the staple
10 against forward movement beyond a predetermined point such that further forward movement of the actuator bends the staple to bring the free ends of the legs towards one another to close the staple, and means for releasing the closed staple, wherein the back of the
15 staple has a rearward extension and the restraining means comprises means for restraining the extension.

2. A device as claimed in claim 1, wherein the rearward extension is rupturably joined to the back of
20 the staple, the staple being released by forward movement of the actuator beyond the point at which the staple is closed while the extension is restrained, thereby to rupture the join.

25 3. A device as claimed in claim 1 or 2, wherein the back of the staple is disposed substantially transverse the longitudinal axis of the housing and the two forwardly pointing legs extend at an angle from opposite ends of the back, the staple back having a
30 centre section and two outer sections, the actuator engaging the outer sections of the staple back and the

restraining means restraining the centre section of the staple back such that the said further forward movement of the actuator bends the outer sections of the staple back forwardly relative to the centre section.

5

4. A device as claimed in claim 3, wherein the staple back is adapted for preferential bending at the junction between the centre and outer sections.

10

5. A device as claimed in claim 4, wherein the extension extends rigidly from the staple back and has a stop means which comes to abut against a cooperating stop means within the housing when the back of the staple reaches the predetermined point.

15

6. A device as claimed in claim 3, 4 or 5, wherein the centre section of the staple back has a greater area in a plane normal to the longitudinal axis of the housing than the outer sections.

20

7. A device as claimed in claim 3, 4 or 5, wherein there are two staples disposed spaced apart one above the other and each has a respective rearward extension, the rearward extensions being connected together and both staples being driven forwardly and closed simultaneously by at least one actuator.

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8. A device as claimed in claim 7, further including an elongated locator member slidable axially within the housing between a forward position wherein the locator member projects beyond the free end of the housing to

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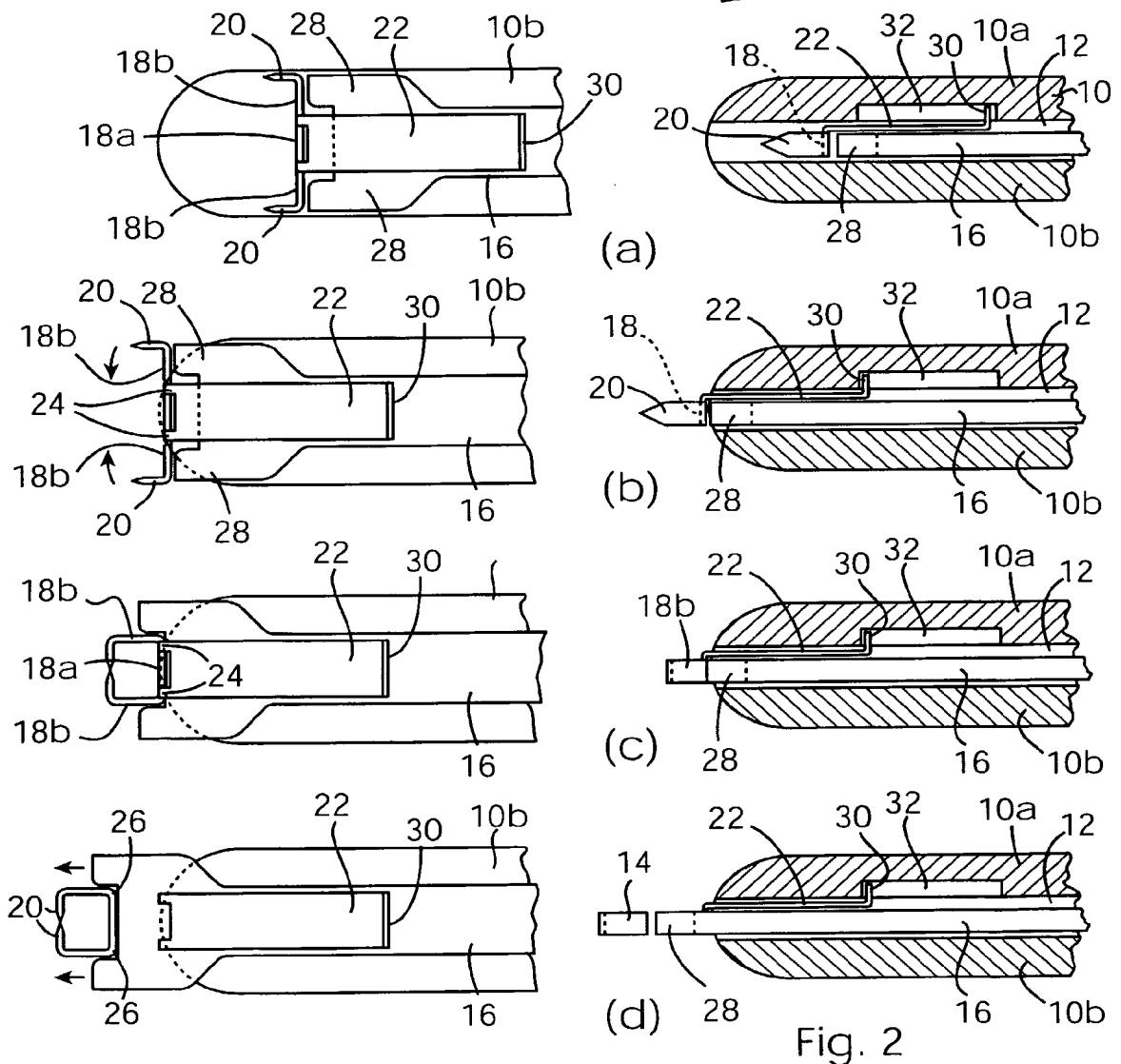
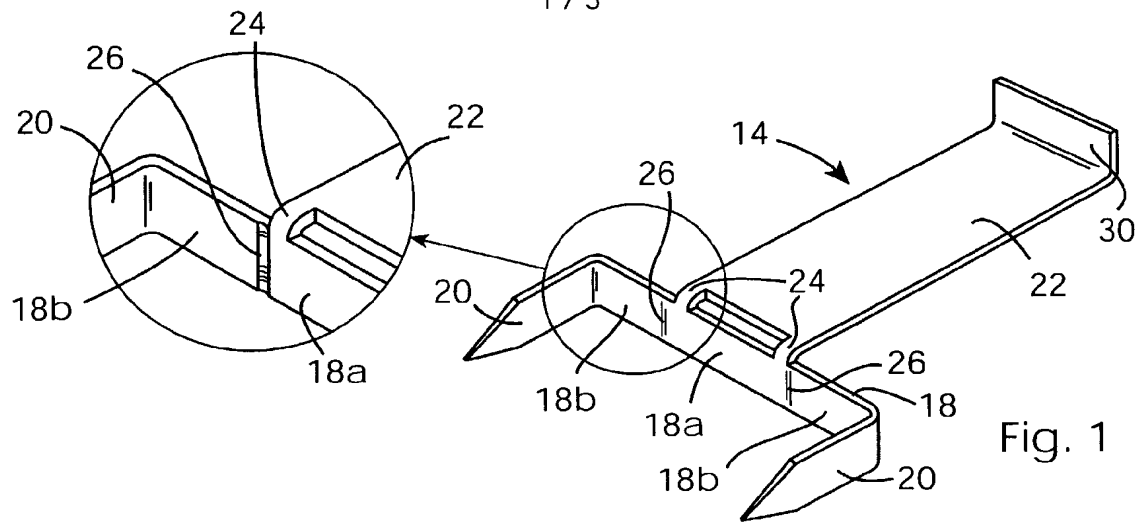
enter a puncture site in a liquid-carrying vessel in a human or animal, thereby to locate the free end of the housing at the puncture site, and a rearward position wherein the locator member is retracted into the housing, the locator member passing between the two rearward extensions and being retracted into the housing prior to closure of the staples.

9. A device as claimed in claim 8, wherein the locator member comprises a hollow tube and a guidewire extends within the locator tube and emerges from the forward end of the tube.

10. A device as claimed in any preceding claim, wherein the staple and rearward extension are made as an integral structure by stamping and bending a metal sheet.

11. A surgical staple comprising a back and two forwardly pointing legs, wherein the back of the staple has a rearward extension to allow the back of the staple to be restrained against movement in a surgical stapling device while the legs are bent towards one another by forward movement of an actuator to close the staple.

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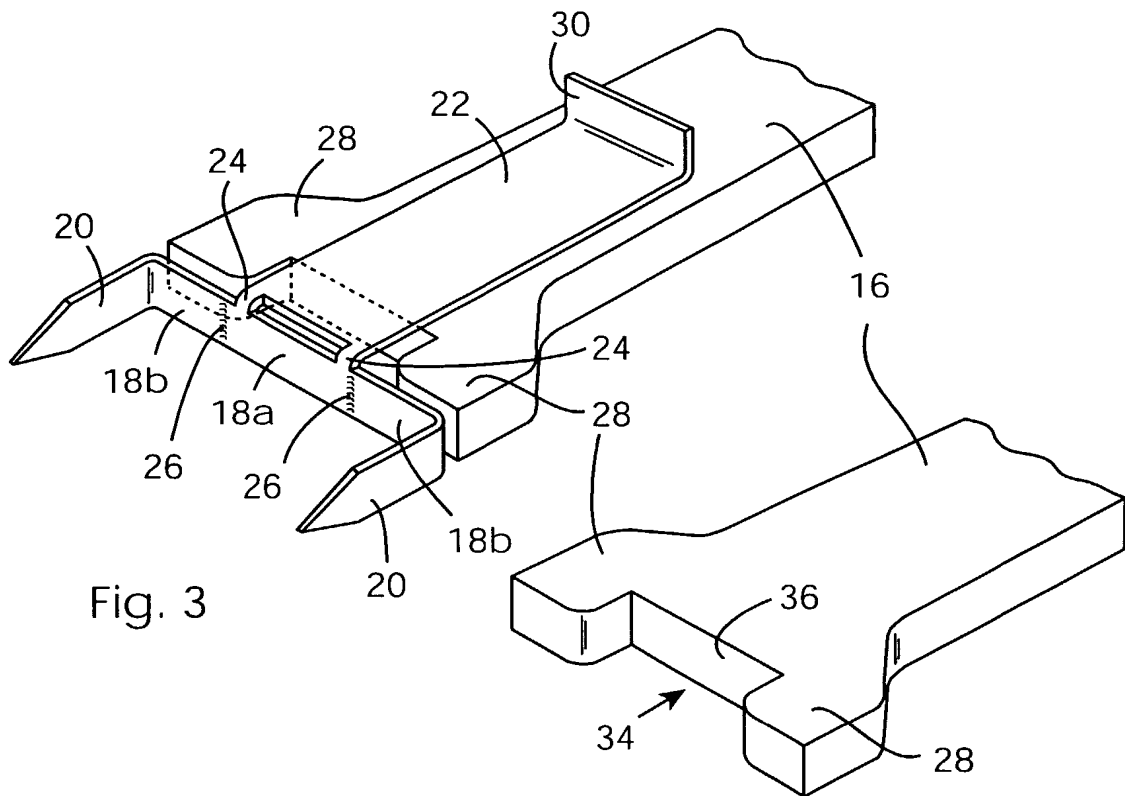


Fig. 3

Fig. 4

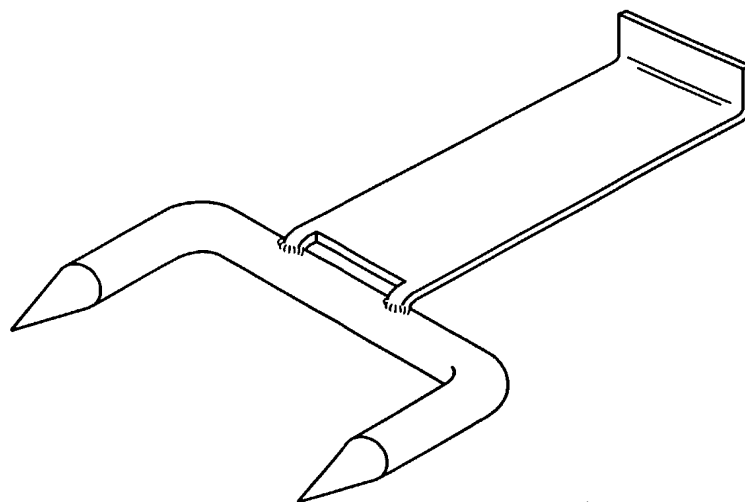


Fig. 5

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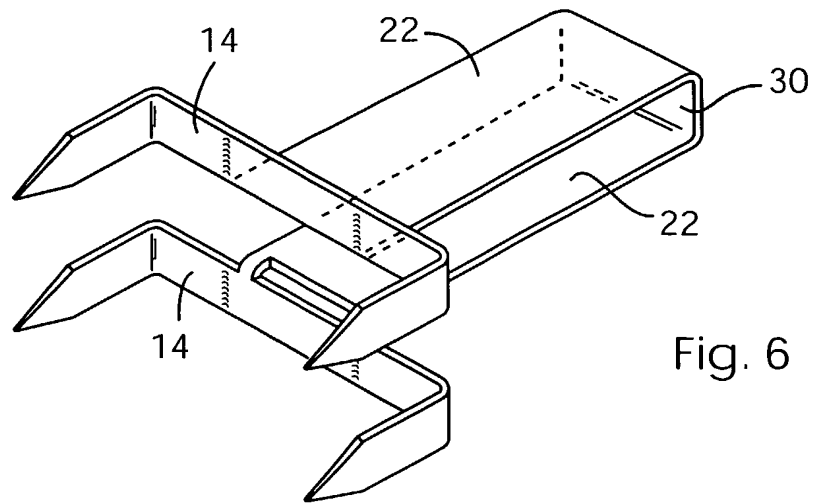


Fig. 6

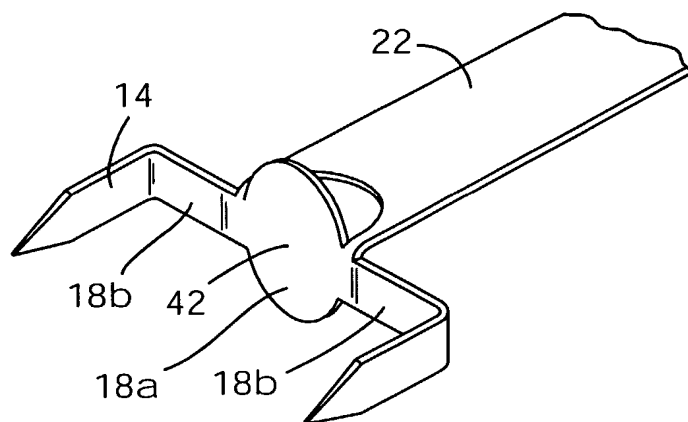


Fig. 7

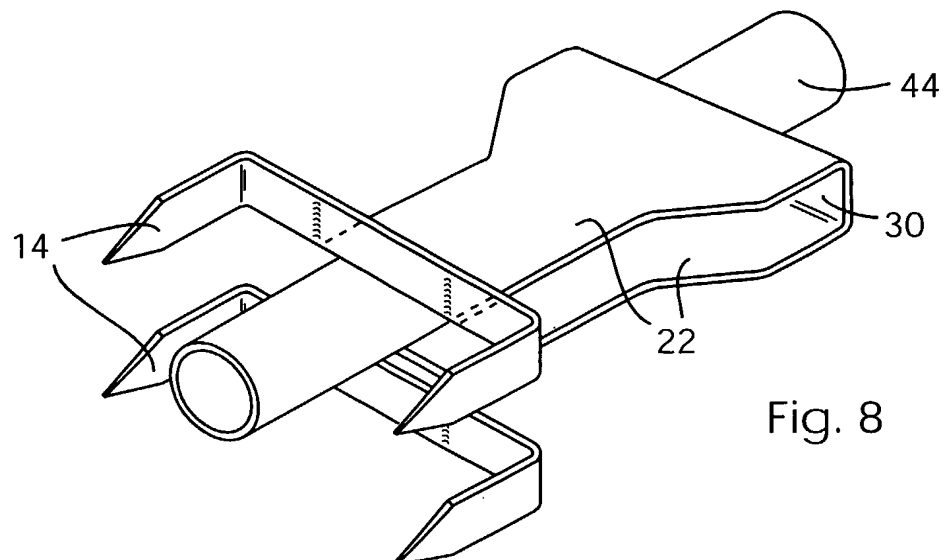


Fig. 8

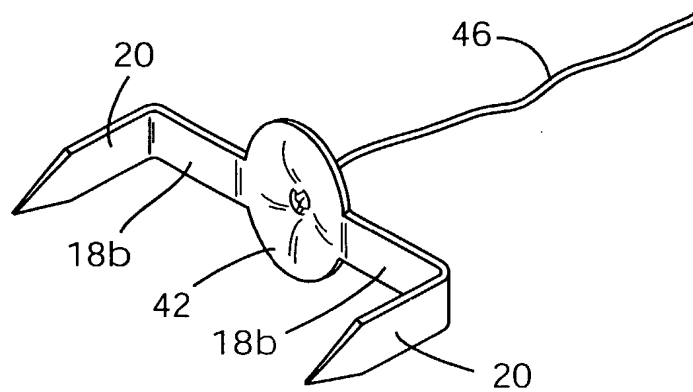


Fig. 9

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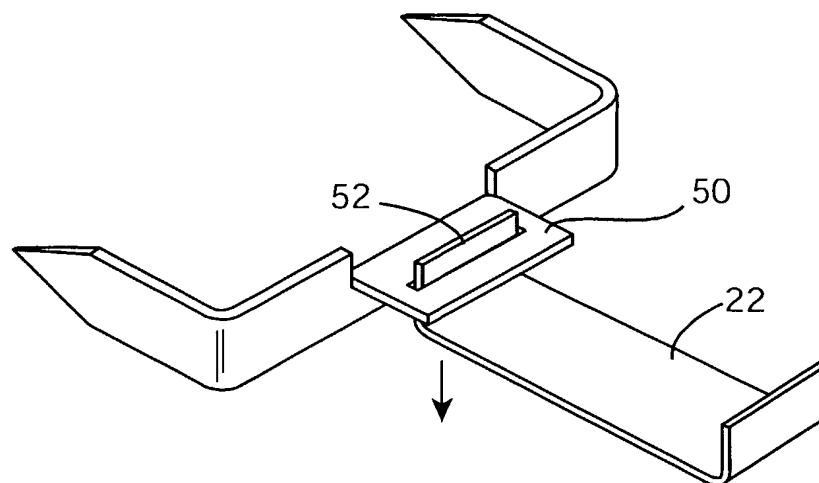


Fig. 10

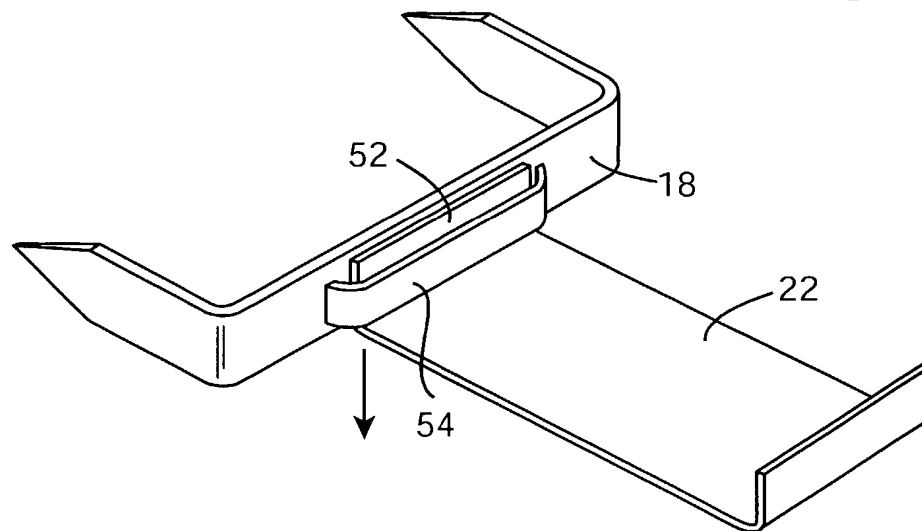


Fig. 11

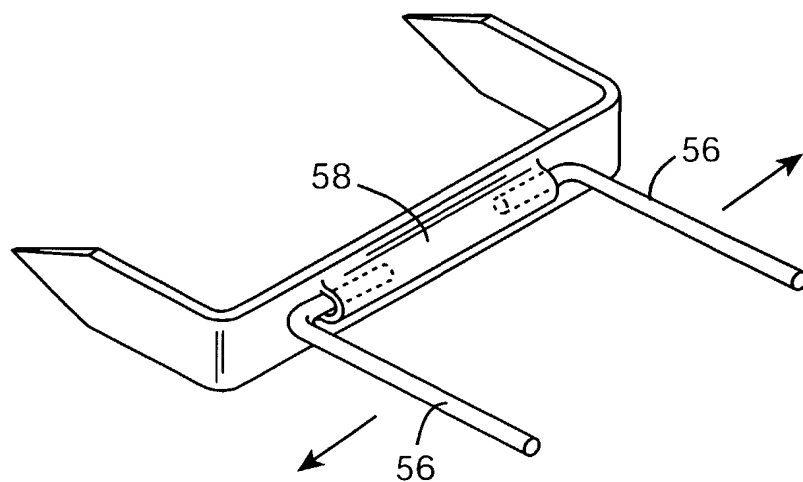


Fig. 12

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 03/00100

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 A61B17/068 A61B17/064

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 902 310 A (COLE MARK ET AL) 11 May 1999 (1999-05-11) column 8, line 4 - line 37; figures 6-8 ---	11
A	US 5 470 010 A (ROTHFUSS ROBERT G ET AL) 28 November 1995 (1995-11-28) cited in the application column 4, line 18 - column 5, line 62; figures 1-6A ---	1
A	US 4 607 638 A (CRAINICH LAWRENCE) 26 August 1986 (1986-08-26) column 4, line 24 - line 37; figures 1,2 ---	1,3,6
A	US 5 941 890 A (BOEHM MICHAEL E ET AL) 24 August 1999 (1999-08-24) figures 4-9 -----	1,3,6



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 03/00100

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5902310	A	11-05-1999	CA 2262550 C DE 69722171 D1 EP 1284123 A1 EP 0873091 A1 JP 2000513610 T WO 9806346 A1	12-03-2002 26-06-2003 19-02-2003 28-10-1998 17-10-2000 19-02-1998
US 5470010	A	28-11-1995	US 5333772 A US 5246156 A US 5174487 A AT 179317 T AU 652276 B2 AU 2213392 A AU 672535 B2 AU 7897794 A CA 2077964 A1 DE 69229031 D1 DE 69229031 T2 EG 19763 A EP 0536903 A2 ES 2130159 T3 GR 92100363 A , B JP 5192340 A TR 27512 A AT 139893 T AU 650959 B2 AU 1397492 A BR 9201193 A CA 2064503 A1 DE 69211882 D1 DE 69211882 T2 EP 0507605 A1 ES 2089397 T3 GR 92100110 A , B JP 3199831 B2 JP 5115486 A	02-08-1994 21-09-1993 29-12-1992 15-05-1999 18-08-1994 25-03-1993 03-10-1996 02-02-1995 13-03-1993 02-06-1999 23-09-1999 29-02-1996 14-04-1993 01-07-1999 21-06-1993 03-08-1993 07-06-1995 15-07-1996 07-07-1994 08-10-1992 01-12-1992 05-10-1992 08-08-1996 28-11-1996 07-10-1992 01-10-1996 16-03-1993 20-08-2001 14-05-1993
US 4607638	A	26-08-1986	NONE	
US 5941890	A	24-08-1999	AU 745589 B2 AU 3226199 A DE 69910684 D1 EP 0966924 A1 JP 2000102546 A	21-03-2002 13-01-2000 02-10-2003 29-12-1999 11-04-2000